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Theodore A. Wood Elizabeth J. Haanes Elizabeth J. Haanes Bruce E. Chalker Joseph S. Ostroff Frank R. Cottingham Christine M. Lhulier Rae Lynn Prengaman Jane Shershenovich* Lawrence J. Carroll* George S. Bardmesser Daniel A. Klein* Rodney G. Maze Jason D. Eisenberg Michael D. Specht Andrea J. Kamage Tracy L. Muller Jon E. Wright LuAnne M. Yuricek*

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*Admitted only in Maryland * Admitted only in Virginia • Practice Limited to Federal Agencies

July 25, 2003

WRITER'S DIRECT NUMBER: (202) 772-8525 **INTERNET ADDRESS:** BRIAND@SKGF.COM

Commissioner for Patents PO Box 1450 Alexandria, VA 22313-1450

Via Hand Carry to Examiner Gerald G. Leffers, Jr. Art Unit 1636

Re:

U.S. Utility Patent Application

Appl. No. 09/438,358; Filed: November 12, 1999

For:

Compositions and Method for Recombinational Cloning

of Nucleic Acid Molecules

Inventors:

GERARD et al.

Our Ref:

0942.4640001/RWE/BJD/JKM

RECEIVED

JUL 3 0 2003

TECH CENTER 1600/2900

Sir:

Transmitted herewith for appropriate action are the following documents:

- COURTESY COPY of the postcard receipt dated September 18, 2000, the postcard 1. receipt dated March 8, 2001, the Information Disclosure Statement (IDS), and Form PTO-1449 (62 pages) as originally filed on September 18, 2000, and as filed as a courtesy copy on March 8, 2001;
- SECOND COURTESY COPY of each missing reference cited on Form PTO-1449 2. (38 documents: AT1, AS4, AT4, AR5, AR9, AR19, AT21, AS22, AS24, AS26, AS29, AR32, AS32, AR35, AT36, AS38, AT40, AR46, AS46, AR47, AR49, AS49, AR50, AS52, AR53, AR54, AR57, AT58, and AS59-AS62) as originally filed on September 18, 2000, and as filed as a courtesy copy on March 8, 2001; and
- One (1) return postcard. 3.

Commissioner for Patents July 25, 2003 Page 2

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Brian J. Del Buono

Attorney for Applicants Registration No. 42,473

RWE/BJD/JKM/acr Enclosures

SKGF_DC1:159399.1

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ASFILED Sextender 18,2000

Due Date: Feb. 12, 2000

Art Unit: 1636

Examiner: Leffers, Jr., G.

Docket: 0942.4640001

Atty: RWE/BJD

Compositions and Methods for Recombinational Cloning of Nucleic Acid Molecules For:

.When receipt stamp is placed hereon, the USPTO acknowledges receipt of the following documents:

1. Transmittal letter (in duplicate);

Filed:

Applicant:

Application No.:

2. Information Disclosure Statement (in duplicate);

3. 62 pages of Form PTO-1449 citing 234 documents; and

Gerard et al.

09/438,358

November 12, 1999

4. A copy of each of the 234 cited documents.



Please Date Stamp And Return To Our Courier

ASFILED March 9,2001

Due Date: March 8, 2001

Examiner: Leffers, Jr., G.

Docket: 0942.4640001

Atty: RWE/BJD

Art Unit: 1636

[Rule 56 IDS 3/19/01 0942.464PC011

Applicant: Gerard et al.

Application No.: 09/438,358

> Filed: November 12, 1999

Compositions and Methods for Recombinational Cloning of Nucleic Acid Molecules For:

When receipt stamp is placed hereon, the USPTO acknowledges receipt of the following documents:

1. SKGF Cover Letter (in duplicate);

2. PTO Fee Transmittal Form (PTO/SB/17);

Check No. 30592 in the amount of \$290.00 to cover the cost of a one month extension of time for a large entity (\$110.00) and the filing of an Information Disclosure Statement (\$180.00);

Petition For Extension of Time Under 37 C.F.R. § 1.136(a)(1) (in duplicate);

5. First Supplemental Information Disclosure Statement and Fee Under 37 C.F.R. § 1.97(c) (in duplicate);

6. 4 pages of Form PTO-1449 citing 21 documents;

7. A copy of each of the 21 cited documents;

8. Courtesy copies of missing documents AT1, AS4, AT4, AR5, AR9, AR19, AT21, AS22, AS24, AS26, AS29, AR32, AS32, AR35, AT36, AS38, AT40, AR46, AS46, AR47, AR49, AS49, AR50, AS52, AR53, AR54, AR57, AT58 and AS59-AS62, cited on Form PTO-1449 with the Information Disclosure Statement filed September 18,

9. Amendment & Reply Under 37 C.F.R. § 1.111; and

10. Return postcard.

Please Date Stamp And Return To Our Courier

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

GERARD et al.

Appl. No. 09/438,358

Filed: November 12, 1999

For: Compositions And Methods For

Recombinational Cloning of Nucleic Acid Molecules Art Unit: 1636

Examiner: Leffers, Jr., G.

Atty. Docket: 0942.4640001/RWE/BJD

Information Disclosure Statement

Assistant Commissioner for Patents Washington, D.C. 20231

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. A copy of each of these documents is provided.

The Examiner is also referred to the following commonly owned, co-pending patent applications, which are directed to related technical subject matter:

U.S. Application No. 09/005,476, filed January 12, 1998;

U.S. Application No. 09/177,387, filed October 23, 1998;

U.S. Application No. 09/233,492, filed January 20, 1999;

U.S. Application No. 09/233,493, filed January 20, 1999;

U.S. Application No. 09/296,280, filed April 22, 1999; U.S. Application No. 09/296,281, filed April 22, 1999;

U.S. Application No. 09/432,085, filed November 2, 1999;

U.S. Application No. 09/498,074, filed February 4, 2000;

U.S. Application No. 09/517,466, filed March 2, 2000; and

U.S. Application No. 09/518,188, filed March 2, 2000.

The identification of these U.S. Applications is not to be construed as a waiver of secrecy as to those applications now or upon issuance of the present applications as patents. The Examiner is respectfully requested to consider the cited applications and the art cited therein during examination.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith. It is further understood that the Examiner will consider information that had been cited or submitted to the U.S. Patent and Trademark Office in a prior application relied on under 35 U.S.C. § 120. 1138 OG 37, 38 (May 19, 1992).

It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO-1449, and to indicate in the official file wrapper of this patent application that the documents have been considered.

This Information Disclosure Statement is being filed more than three months after the U.S. filing date but before a first Office Action on the merits. No statement or fee is required.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036. A duplicate copy of this pleading is enclosed.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Brian J. Del Buono Agent for Applicants Registration No. 42,473

Date: Splember 18 2000

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Page 1 of 62

		FORM PTO)-1449		0942.4640001 APPLICANT	09/43	38,358	
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				U.S	. PATENT DOCUMENTS			
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IITIAL	144	4,673,		06/16/1987	Backman, K.C.	435	68	04/30/1984
	AA1	4,743,		05/10/1998	Backman et al.	435	108	02/13/1985
	AB1			09/25/1990	Sauer B.L.	435	172.3	04/29/1987
	AC1	4,959, 5,227,		07/13/1993	Blattner, F.R.	435	6	10/01/1990
	AD1	5,354,		10/11/1994	Auerbach, J.I.	435	91.1	10/15/1993
	AE1	5,434		07/18/1995	Bebee, R.L., et al.	435	172.3	03/15/1994
	AF1	 		11/28/1995	Mascarenhas et al.	435	172.3	12/21/1993
	AG1	5,470			Auerbach, J.I.	435	91.2	02/03/1995
	AH1	5,591		01/07/1997	Auerbach, J.I.	435	91.2	09/26/1995
	AI1	5,614		03/25/1997	Hooykaas et al.	435	172.3	01/20/1995
	AJ1	5,635		06/03/1997		435	172.3	07/27/1994
	AK1	5,658	,772	08/19/1997	Odell et al.			
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	AL1	EP 0	160 571 A2	11/06/1985	Europe			N Ye
	AM1	EP 0	300 422	01/25/1989	Europe			Ye
	AN1	₩O 91	/02801	03/07/1991	WIPO			Ye
	AO1	WO 91	1/16427	10/31/1991	WIPO			N Ye
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	AS	1	Abremski, Properties	K., and Hoess, of the Cre Rec	R., "Bacteriophage P1 Site combinase Protein," <i>J. Biol</i>	e-specific Recombi . Chem. 259:1509-	nation - Puri 1514 (1984).	fication and
	AT	1	Abremski, Topoisomer	K., et al., "Be ease Activity o	acteriophage P1 Cre- <i>loxP</i> Si f the Cre Recombination Pro	te-specific Recom otein," <i>J. Biol. (</i>	abination: Sit Chem. 261(1):39	e-specific DNA 21-396 (1986).
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	AA2	5,677,	170	10/14/1997	Devine et al.	435		325	06/07/1995
	AB2	5,677,	177	10/14/1997	Wahl et al.	530		327	07/29/1996
	AC2	5,710,	248	01/20/1998	Grose, C.F.	800		208	06/07/1995
	AD2	5,723,	765	03/03/1998	Oliver et al.	43		6	02/01/1996
	AE2	5,733,	733	03/31/1998	Auerbach, J.I.	43		320.1	06/10/1996
	AF2	5,733,	743	03/31/1998	Johnson et al.	43		172.3	03/08/1996
	AG2	5,744,	336	04/28/1998	Hodges et al.	43		91.41	12/19/1994
	AH2	5,766,	891	06/16/1998	Shuman, S.	43		93.2	09/20/1996
	AI2	5,776,	449	07/07/1998	Baum et al.	42		69.7	06/05/1995
	AJ2	5,830,	,707	11/03/1998	Bushman, F.D.			136.1	05/14/1996
	AK2	5,837	,242	11/17/1998	Holliger et al.	42	.4	130.1	03,11,111
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	AS	2	Adams, D. from the i	E., et al., "Co in Vitro Reaction	re- <i>lox</i> Recombination in <i>E</i> on," <i>J. Mol. Biol. 226</i> :66	scherichia co 1-67 3 (1992).	i Cells:	Mechanisti	c Differences
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TIAL			NT NUMBER	DATE	Devine, S.E., et al.	435	69.1	11/18/1994
	AA3	5,843,		12/01/1998	Elledge et al.	435	172.3	02/28/1997
	AB3	5,851,		12/22/1998	Winter et al.	435	6	06/07/1995
	AC3	5,858,		01/12/1999	Winter et al.	435	6	03/31/1994
	AD3	5,871,	907	02/16/1999		435	91.1	11/21/1997
	AE3	5,874,	259	02/23/1999	Szybalski, W.	435	6	06/07/1996
	AF3	5,888,	,732	03/30/1999	Hartley et al.	435	325	04/17/1998
	AG3	5,916,	,804	06/29/1999	Bushman, F.D.	435	172.3	06/07/1995
	AH3	5,919	,676	07/06/1999	Graham et al.	435	172.3	11/05/1996
	AI3	5,928	,914	07/27/1999	Leboulch et al.		91.2	08/12/1997
	AJ3	5,989	,872	11/22/1999	Luo et al.	435		05/29/1996
	AK3	6,010	,884	01/04/2000	Griffiths et al.	435	69.7	03/29/1990
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	AM3	WO 97	7/25446	07/17/1997	WIPO			Y.
	4117	UO 97	7/32481	09/12/1997	WIPO			<u> </u>
	AN3				WIPO			Ye
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	AT	3	Araki, H. 225:25-37	, et al., "Site (1992).	e-specific Recombinase, R,	Encoded by Yeas	t Plasmid pSR1,	J. Mol. Biol.
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Page 4 of 62

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	AS	<u>5</u>	Babineau, 12391 (198	D. <i>et al.</i> , "The 5).	FLP Protein of the 2-micro	Plasmid of '	Yeast," .	J. Biol. Cf	nem. 260:12313-
	AT	5	Balakrishr att-Int-me	nan, R., <i>et al</i> ., diated rearrange	"A gene cassette for adapt ement and p_{L} expression vec	ting <i>Escherich</i> tors," <i>Gene</i> 1	hia coli 138: 101- 1	strains as 04 (Januar	s hosts for y 1994).
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	AS	6	istress a	B., and Saur, B. ctivation of the ly 1997).	, "Segmental genomic rep p53 promoter in single-	lacement by Cre-m copy transformant	ediated recombi s," <i>Nucl. Acids</i>	nation: genotox Res. 25:2828-
	AT	6	Bernard, DNA-topo	P., and Coutur	ier, M., "Cell Killing by mplexes," <i>J. Mol. Biol. 2</i>	y the F plasmid Co 226:735-745 (1992)	db Protein Invo	olves Poisoning
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	AT	7	Bhandari overprod (July 19	, P and Gowrisha uction of cloned 97).	nkar, J., "An <i>Escherichi</i> gene products with NaCl	<i>a coli</i> host : Las the indu	strain us ucer," <i>J</i> .	eful for ef Bacteriol 1	ficient 79:4403-4406
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	AT	8	Bochner, 143:926-9	B. R., et al., ៕ 33 (1980).	Positive Selection for Loss	of Tetra	cycl ine	Resistance,	J. Bacteriol.
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			Boyd, A. C	., "Turbo cloning	g: a fast, efficient met	hod for cloni	ng PCR p	roducts and	lother blunt-
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	AS	19	Guo, F., Proc. Nat	et al., "Asymmet 1. Acad. Sci. USA	ric DNA bending in the Cre- 1 96:7143-7148 (June 1999).	loxP site-	specific	: recombinat	ion synapse,"		
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FORM PTO-1449

INFORMATION DISCLOSURE STATEMENT

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	AR	<u>20</u>	Hasan, N., and Szybalski, W., "Control of cloned gene expression by promoter inversion in vivo: construction of improved vectors with a multiple cloning site and the p_{tac} promoter," Gene 56:145 151 (1987). Hasan, N., et al., "Escherichia coli genome targeting, I. Cre-lox-mediated in vitro generation of the processing of the processing of the processing and retrieval," Gene 150:51-56 (1994).								
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	AT	<u>20</u>	Hashimoto-Gotoh, T., et al., "Improved vector, pHSG664, for direct streptomycin-resistance selection: cDNA cloning with G:C-tailing procedure and subcloning of double-digested DNA fragments," Gene 41:125-128 (1986).								
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	AS	24	Kilby, N. Genetics	ools for ge	ols for genome engineering," <i>Trends in</i>				
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	AS	<u>25</u>	Kozak, M. Acids Res	, "An analysis of 15:8125-8132 (1	f 5'-noncoding sequences fr 987).	rom 699 ver	tebrate (messenger RI	NAS," Nucl.
	AT	<u>25</u>	Kozak, M. J. Biol.	, "Structural fe Chem. 266:19867-1	atures in eukaryotic mRNAs 9870 (1991).	that modul	ate the	initiation	of translation,"
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	AS	<u>26</u>	Lafontaine, D., and Tollervey, D., "One-step PCR mediated strategy for the construction of conditionally expressed and epitope tagged yeast proteins," <i>Nucl. Acids Res. 24</i> :2469-2472 (1996).								
	AT	<u>26</u>	Lakso, M., mice," <i>Pro</i>	et al., "Target c. Natl. Acad. S	ed oncogene activation by Ci. USA 89:6232-6236 (1997)	v site-specific reco 2).	ombination in	n transgenic			
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	AT	50	Sternber Bacterio	rg, N., et al	., "Site-specific Recom Cold Spring Harbor Symp.	mbination and It Quant. Biol. 45	s Role in 5:297-309 (the Life Cyc (1981).	le of
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	AS	<u>56</u>	Winoto, A.	.,et al., "Direct 192:677-680 (19	cional Control of Site-specif 186).	ic Recomb	ination	by Bacteric	ophage A," J.
	AT	<u>56</u>	Yang, W., (November	and Mizuuchi, K 1997).	., "Site-specific recombinat				e 5:1401-1406
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	AS	57	Yoon, Y.G., their ampl	, et al., "Cre/lo ification based o	DXP-mediated in vivo excision the 2 μm plasmid-derived	on of large segmen I system," <i>Gene 223</i>	nts from yea 3:67-76 (Nov	st genome and ember 1998).
	AT	57	York, D., o	et al., "Simple a olecular transpo	and efficient generation in sition," Nucl. Acids Res. 20	<i>vitro</i> of nested c 6:1927-1933 (April	deletions an 1998).	d inversions:
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citation if	not in co	nforma	nce and not o	onsidered. Inc	lude copy of this f	orm with next o	cati	ion to Applica	inc.		